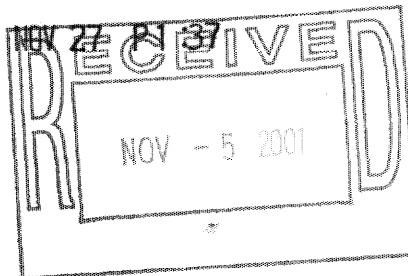




Innovative Nutrition Solutions

4412 '01



October 24, 2001

Food and Drug Administration  
Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
200 C Street, SW  
Washington, DC 20204

Dear Sirs:

Notice is hereby given that Rexall Sundown, Inc. ("Sundown") located at 6111 Broken Sound Parkway, N.W., Boca Raton, Florida 33487 has marketed a dietary supplement under the Sundown brand name bearing the following statement(s) on the label and/or in the labeling:

Hawthorn Berries: [For a] healthy heart. Hawthorn Berries are known for their positive effects in maintaining healthy heart and circulatory function. Hawthorn Berries, along with regular exercise, can benefit your heart and circulatory system.

Folic Acid, Vitamin E, Co Q-10 [and] Garlic: A healthy circulatory system is a key component of healthy heart function. Try these Sundown healthy heart aids.

The undersigned certifies that the information contained in this notice is complete and accurate and that Sundown has substantiation that the statement is truthful and not misleading. Pursuant to § 101.93 (a)(1), two copies of this notification are enclosed.

Sincerely,

Deborah Shur Trinker, Esquire  
Senior Vice President  
Regulatory Affairs

Enclosure

975-0162

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6111 BROKEN SOUND PKWY. NW • BOCA RATON, FLORIDA 33487  
561-241-9400 • FAX 561-995-5188